Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with providing advice and guidance to the Director, CDC, regarding the scientific merit and direction of the Hanford Thyroid Morbidity Study.

Matters to be Discussed: This is the second meeting of the Hanford Thyroid Morbidity Study Advisory Committee and the first to be held in the northwest. The Committee will listen to presentations by a number of interest groups and will comment on the status of various components of the Hanford Thyroid Morbidity Study. Specifically, the discussions will focus on scientific rationale, tribal activities and plans, and clinical detection of thyroid disease. On July 9 at 7:30 p.m., the meeting will continue in order to allow more time for public input and comment not addressed during the morning and afternoon sessions.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mike Sage, Committee Manager, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, Center for Environmental Health and Injury Control, CDC, 1600 Clifton Road, NE., (F-28), Atlanta, Georgia 30333, telephone 404/488-4613 or FTS 236-4613.

Dated: June 18, 1991.

Robert L. Foster,

Assistant Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 91-14919 Filed 6-21-91; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 91E-0106]

Determination of Regulatory Review Period for Purposes of Patent Extension; Bepadin® and Vascor®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Bepadin® and Vascor® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims these human drug products.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard Klein, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently simultaneously approved for marketing the human drug products Bepadin® and Vascor®. Both Bepadin® and Vascor® (bepridil hydrochloride) are indicated in chronic stable angina. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Bepadin® and Vascor® (U.S. Patent No. RE. 30,577) from Riom Laboratories C.E.R.M., and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated April 12, 1991, advised the Patent and Trademark Office that these human drug products had undergone a regulatory review period and that the approval of the active ingredient, bepridil hydrochloride, represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine these products' regulatory review period.

FDA has determined that the applicable regulatory review period for Bepadin® is 4,658 days. Of this time, 2,108 days occurred during the testing phase of the regulatory review period, while 2,550 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The Date an Exemption Under Section 505(i) of the Federal Food, Drug, and Cosmetic Act Became Effective

March 30, 1978. The applicant claims March 24, 1977, as the date the investigational new drug (IND) application for Bepadin® became effective. However, FDA records indicate that IND became effective on March 30, 1978.

2. The Date the Application Was Initially Submitted With Respect to the Human Drug Product Under Section 505(b) of the Federal Food, Drug, and Cosmetic Act

January 5, 1984. The applicant claims December 28, 1983, as the date the new drug application (NDA) for Bepadin® (NDA 19-001) was initially submitted. However, FDA records indicate that the application was received on January 5, 1984.

3. The Date the Application was Approved

December 28, 1990. FDA has verified the applicant's claim that NDA 19-001 was approved on December 28, 1990.

FDA has determined that the applicable regulatory review period for Vascor® is 3,207 days. Of this time, 649 days occurred during the testing phase of the regulatory review period, while 2,558 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The Date an Exemption Under Section 505(i) of the Federal Food, Drug, and Cosmetic Act Became Effective

March 20, 1982. The applicant claims March 17, 1982, as the date the investigational new drug (IND) application for Vascor® became effective. However, FDA records indicate that the IND became effective on March 20, 1982.

2. The Date the Application was Initially Submitted With Respect to the Human Drug Product Under Section 505(b) of the Federal Food, Drug, and Cosmetic Act

FDA has verified the applicant's claim that NDA 19-002 was received on December 28, 1983.

3. The Date the Application was Approved

December 28, 1990. FDA has verified the applicant's claim that NDA 19-002 was approved on December 28, 1990.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before August 23, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before December 23, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 17, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-14934 Filed 6-21-91; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Privacy Act of 1974; Systems of Records

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of proposed new routine use for two existing systems of records.

SUMMARY: HCFA is proposing to add a new routine use to two existing systems of records: the "Municipal Health Services Program," HHS/HCFA/ORD No. 09-70-0022, and the "Person-Level Medicaid Data System," HHS/HCFA/ORD No. 09-70-0033. In addition, we are taking this opportunity to make minor editorial changes to the "Municipal Health Services Program." We invite comments on these changes.

EFFECTIVE DATES: The proposed changes shall take effect July 24, 1991, unless comments received on or before that date would warrant modification to the notice.

ADDRESSES: The public should address comments to: Richard A. DeMeo, HCFA Privacy Act Officer, Office of Budget and Administration, Health Care Financing Administration, room 108 Security Office Park Building, 7008 Security Boulevard, Baltimore, Maryland 21207. Comments received will be available for inspection at this location.

FOR FURTHER INFORMATION CONTACT: Sydney P. Galloway, Office of Operations Support, Office of Research and Demonstrations, Health Care Financing Administration, room 2226 Oak Meadows Building, 6325 Security Boulevard, Baltimore, Maryland 21207, Telephone (301) 966-6645.

SUPPLEMENTARY INFORMATION: The notice for the "Municipal Health Services Program," HHS/HCFA/ORD No. 09-70-0022, was most recently published in the Privacy Act Issuances, 1989 Compilation, Volume 1, Page 380. This system consists of bills and records submitted by clinics in the Municipal Health Services Program demonstrations to claim Federal reimbursement for services provided to Medicare beneficiaries.

The notice for the "Person-Level Medicaid Data System," HHS/HCFA/ORD No. 09-70-0033, was most recently published in the Privacy Act Issuances, 1989 Compilation, Volume I, Page 387. This system consists of unit record data files on all Medicaid enrollment, providers, and claims for hospital, physician, nursing home, prescription drug, and other Medicaid covered services in selected States beginning in 1980. This information contained in the records is obtained from existing State Medicaid Management Information Systems. The purpose of this system of records is to study Medicaid use and expenditures for basic research/information purposes and policy analysis.

HCFA's research routine use is normally included in all of HCFA's program system notices. We are proposing to add this routine use which was inadvertently left out of each of these systems of records. This will modify the system notice to permit HCFA to release data to research contractors and awardees and to contractors and awardees of other Federal agencies. These releases will be for research and evaluation projects that are determined by HCFA to be significant and which do not violate the agreements under which these data were voluntarily supplied by individual States and for which there is reasonable probability that the project will accomplish its objectives. Strict protection of the data by the requestor is required.

This routine use is similar in nature to the standard routine use that permits disclosure to a contractor for the purpose of collating, analyzing, aggregating or otherwise refining or processing records in a system or for developing, modifying and/or manipulating ADP software.

To comply with the requirements of the Privacy Act, we are proposing to establish the routine use below, adding to previously published uses.

To an individual or organization for research or evaluation, if HCFA:

a. Determines that the proposed use does not violate the legal limitations under which the record was provided, collected, or obtained;

b. Determines that the proposed use does not violate the understandings with the States that voluntarily supplied the data;

c. Determines that the purpose for which the proposed use is to be made:

(i) Cannot be reasonably accomplished unless the record is provided in an individually identifiable form, and

(ii) Is of sufficient importance to warrant the effect on and/or risk to the privacy of the individual that additional exposure of the record might bring, and

(iii) There is a reasonable probability that the objective of the use would be accomplished;

d. Requires the recipient of the information to:

(i) Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and

(ii) Remove or destroy the information that allows the individual to be identified at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the project, unless the recipient presents an adequate justification of a research or health nature for retaining such information, and receives written authorization from HCFA that it is justified based on research objectives for retaining such information, and

(iii) Make no further use of the record except: